- 1 Legend: (Proposed New Rules)
- 2 Regular Print = Proposed new language
- 3 Subchapter J

§133.181 Purpose

The purpose of this section is to implement Health and Safety Code, Chapter 241, Subchapter H, Hospital Level of Care Designations for Neonatal and Maternal Care, which requires a level of care designation of maternal

services to be eligible to receive reimbursement through the Medicaid

10 program for maternal services.

§133.182 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Antepartum--the period beginning on the date of conception and ending on the commencement of labor.

(2) Attestation--A written statement, signed by the Chief Executive Officer of the facility, verifying the results of a self-survey represent a true and accurate assessment of the facility's capabilities required in this subchapter.

(3) CAP--Corrective Action(s) Plan. A plan for the facility developed by the Office of EMS/Trauma Systems Coordination that describes the actions required of the facility to correct identified deficiencies to ensure compliance with the applicable designation requirements.

(4) Commission--The Health and Human Services Commission.

(5) Department--The Department of State Health Services.

(6) Designation--A formal recognition by the executive commissioner of a facility's neonatal or maternal care capabilities and commitment, for a period of three years.

(7) Executive commissioner--The executive commissioner of the Health and Human Services Commission.

(8) Immediately--Without delay.

42 (9) Infant--A child from birth to 1 year of age.

(10) Intrapartum--during labor and delivery or childbirth.

45 46	(11) Lactation consultantA health care professional who specializes in the clinical management of breastfeeding.
47 48 49	(12) MaternalPertaining to the mother.
50 51	(13) NeonateAn infant from birth through 28 completed days after.
52 53	(14) MFMMaternal Fetal Medicine.
54 55	(15) MMDMaternal Medical Director.
56 57	(16) MPMMaternal Program Manager.
58 59 60	(17) Obstetricsrelated to pregnancy, childbirth, and the postpartum period.
61 62 63	(18) OfficeOffice of Emergency Medical Services (EMS)/Trauma Systems Coordination.
64 65	(19) PCRPerinatal Care Region.
66 67 68	(20) PerinatalOf, relating to, or being the period around childbirth, especially the five months before and one month after birth.
69 70 71	(21) POCPlan of Correction. A report submitted to the office by the facility detailing how the facility will correct any deficiencies cited in the survey report or documented in the self-attestation
72 73 74	(22) Postpartumthe period following pregnancy or childbirth.
75 76 77	(23) QAPI ProgramQuality Assessment and Performance Improvement Program.
78 79 80	(24) RACRegional Advisory Council as described in §157.123 of this title (relating to Regional Emergency Medical Services/Trauma Systems).
81 82 83	(25) SupervisionAuthoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity
84 85 86	(26) TSATrauma Service Area as described in §157.122 of this title relating to (Trauma Service Areas).

(27) Urgent--Requiring immediate action or attention.

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§133.183 General Requirements

(a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Executive Commissioner of the Health and Human Services Commission (executive commissioner) the designation of an applicant/healthcare facility as a maternal facility at the level for each location of a facility, which the office deems appropriate.

(b) A healthcare facility is defined under this subchapter as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

(c) Each location shall be considered separately for designation and the office will determine the designation level for that location, based on, but not limited to, the location's own resources and level of care capabilities; Perinatal Care Region (PCR) capabilities; and compliance with Chapter 133 of this title, concerning Hospital Licensing. The final determination of the level of designation may not be the level requested by the facility.

(1) Level I (Basic Care). The Level I maternal designated facility will:

(A) provide care of pregnant and postpartum women who are generally healthy, and do not have medical, surgical, or obstetrical conditions that present a significant risk of maternal morbidity or mortality; and

(B) have skilled personnel with documented training, competencies and annual continuing education specific for the patient population served.

(2) Level II (Specialty Care). The Level II maternal designated facility will:

(A) provide care for pregnant women and postpartum women with medical, surgical, and/or obstetrical conditions that present a low to moderate risk of maternal morbidity or mortality; and

(B) have skilled personnel with documented training, competencies and annual continuing education specific for the patient population served.

(3) Level III (Subspecialty Care). The Level III maternal designated facility will:

133	
134	(A) provide care for pregnant and postpartum women with low
135	risk conditions to significant complex medical, surgical and/or
136	obstetrical conditions that present a high risk of maternal
137	morbidity or mortality;
138	
139	(B) ensure access to consultation to a full range of medical and
140	maternal subspecialists and surgical specialists, and the
141	capability to perform major surgery on-site;
142	
143	(C) have physicians with critical care training available at all
144	times to actively collaborate with Maternal Fetal Medicine
145	physicians and/or Obstetrics and Gynecology physicians with
146	obstetrical training and privileges;
147	
148	(D) have skilled personnel with documented training,
149	competencies and annual continuing education, specific for the
150	population served;
151	
152	(E) facilitate transports; and
153	
154	(F) provide outreach education to lower level designated facilities
155	including the Quality Assessment and Performance Improvement
156	(QAPI) process.
157	
158	(4) Level IV (Comprehensive Care). The Level IV maternal
159	designated facility will:
160	
161	(A) provide perinatal women with comprehensive care for low
162	risk conditions to the most complex medical, surgical and/or
163	obstetrical conditions and their fetuses, that present a high risk
164	of maternal morbidity or mortality;
165	
166	(B) ensure access to onsite consultation to a comprehensive
167	range of medical and maternal subspecialists and surgical
168	specialists, and the capability to perform major surgery
169	on-site;
170	
171	(C) have physicians with critical care training available at all
172	times to actively collaborate with Maternal Fetal Medicine
173	physicians and/or Obstetrics and Gynecology physicians
174	with obstetrical training;
175	3 ,

176 177		(D)	have skilled personnel with documented training, competencies and annual continuing education, specific for
178 179			the patient population served;
180		(E)	facilitate transports; and
181 182 183 184		includ	rovide outreach education to lower level designated facilities ding the Quality Assessment and Performance Improvement I) process.
185 186	(d) Facilities	seek	king maternal facility designation shall be surveyed through
187 188 189 190	_	ved r	pproved by the office to verify that the facility is meeting elevant maternal facility requirements. The facility shall the survey.
191 192	(e) PCR's		
193 194			Rs are established for descriptive and regional planning nd not for the purpose of restricting patient referral.
195 196 197			R will consider and facilitate transfer agreements through ordination.
198 199 200 201 202		tal ca	en plan identifies all resources available in the PCRs for are including resources for emergency and disaster ess.
203 204 205 206 207	into th (RAC) be adr	ne exi of th minis	Rs are geographically divided by counties and are integrated sting 22 TSAs and the applicable Regional Advisory Council e TSA provided in §157.122 and §157.123 of this title; will tratively supported by the RAC; and will have fair and epresentation on the board of the applicable RAC.
208 209 210	(5) Mu collabo		e PCRs can meet together for the purposes of mutual on.
211 212	<u>§133.184 [</u>	Desig	nation Process.
213 214 215 216 217	inclusive of	the fo	pplication packet. The applicant shall submit the packet, bllowing documents to the Office of EMS/Trauma Systems ice) within 120 days of the facility's survey date:

218	(1) an accurate and complete designation application form for the
219	appropriate level of designation, including full payment of the
220	designation fee as listed in subsection (d) of this section;
221	
222	(2) any subsequent documents submitted by the date requested by
223	the office;
224	
225	(3) a completed maternal attestation and self-survey report for Level I
226	applicants or a designation survey report, including patient care
227	reviews if required by the office, for Level II, III and IV applicants;
228	(4) ((((((((((((((((((
229	(4) a plan of correction (POC), detailing how the facility will correct
230	any deficiencies cited in the survey report, to include: the corrective
231	action; the title of the person responsible for ensuring the
232	correction(s) is implemented; how the corrective action will be
233	monitored; and the date by which the POC will be completed; and
234	(5) avidance of participation in the applicable Peripatal Care Region
235236	(5) evidence of participation in the applicable Perinatal Care Region (PCR).
237	(FCR).
238	(b) Renewal of designation. The applicant shall submit the documents
239	described in subsection (a)(1) - (5) of this section to the office not more
240	than 180 days prior to the designation expiration date and at least 60 days
241	prior to the designation expiration date.
242	prior to the designation expiration date.
243	(c) If a facility seeking designation fails to meet the requirements in
244	subsection (a)(1) - (5) of this section, the application shall be denied.
245	
246	(d) Non-refundable application fees for the three year designation period are
247	as follows:
248	
249	(1) Level I maternal facility applicants, the fees are as follows:
250	
251	(A) \leq =100 licensed beds, the fee is \$250.00; or
252	
253	(B) $>$ 100 licensed beds, the fee is \$750.00.
254	
255	(2) Level II maternal facility applicants, the fee is \$1,500.00.
256	(0)
257	(3) Level III maternal facility applicants, the fee is \$2,000.00.
258	(4)
259	(4) Level IV maternal facility applicants, the fee is \$2,500.00.

- (A) All completed applications, received on or before July 1, 2020, including the application fee, evidence of participation in the PCR, an appropriate attestation if required, survey report, and that meet the requirements of the requested designation level, will be issued a designation for the full three-year term.
 - (B) Any facility that has not completed an on-site survey to verify compliance with the requirements for a Level II, III or IV designation at the time of application must provide a self-survey and attestation and will receive a Level I designation. The office, at its sole discretion may recommend a designation for less than the full three-year term. A designation for less than the full three-year term will have a pro-rated application fee consistent with the one, two or three-year term length.
 - (C) A facility applying for Level I designation requiring an attestation may receive a shorter term designation at the discretion of the office. A designation for less than the full three-year term will have a pro-rated application fee.
 - (D) The office, at its discretion, may designate a facility for a shorter term designation for any application received prior to September 1, 2020.
 - (E) An application for a higher or lower level designation may be submitted at any time.
- (e) If a facility disagrees with the level(s) determined by the office to be appropriate for initial designation or re-designation, it may make an appeal in writing not later than 60 days to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation of how the facility meets the requirements for the designation level.
 - (1) If the office upholds its original determination, the director of the office will give written notice of such to the facility not later than 30 days of its receipt of the applicant's complete written appeal.
 - (2) The facility may, not later than 30 days of the office's sending written notification of its denial, submit a written request for further review. Such written appeal shall then go to the Director of EMS / Trauma Systems Coordination of the Division for Consumer Protection.

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Maternal Rules Draft Document (f) The surveyor(s) shall provide the facility with a written, signed survey 304 report regarding their evaluation of the facility's compliance with maternal 305 306 program requirements. This survey report shall be forwarded to the facility no later than 30 days of the completion date of the survey. The facility is 307 responsible for forwarding a copy of this report to the office if it intends to 308 continue the designation process. 309 310 (g) The office shall review the findings of the survey report and any POC 311 submitted by the facility, to determine compliance with the maternal 312 program requirements. 313 314 (1) A recommendation for designation shall be made to the 315 commissioner based on compliance with the requirements. 316 317 (2) A maternal level of care designation shall not be denied to a facility 318 that meets the minimum requirements for that level of care 319 designation. 320 321 (3) If a facility does not meet the requirements for the level of 322 designation requested, the office shall recommend designation for the 323 facility at the highest level for which it qualifies and notify the facility 324 of the requirements it must meet to achieve the requested level of 325 designation. 326 327 328 329 (CAP). 330 331

(4) If a facility does not comply with requirements, the office shall notify the facility of deficiencies and required corrective action(s) plan

- (A) The facility shall submit to the office reports as required and outlined in the CAP. The office may require a second survey to ensure compliance with the requirements. The cost of the survey will be at the expense of the facility.
- (B) If the office substantiates action that brings the facility into compliance with the requirements, the office shall recommend designation to the executive commissioner.
- (C) If a facility disagrees with the office's decision regarding its designation application or status, it may request a secondary review by a designation review committee. Membership on a designation review committee will:
 - (i) be voluntary;

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348	(ii) be appointed by the office director;
349	
350	(iii) be representative of maternal care providers and
351	appropriate levels of designated maternal facilities; and
352	
353	(iv) include representation from the office and the
354	Perinatal Advisory Council.
355	(5) 75 1 1 1 1 1 1 1 1 2 2
356	(D) If a designation review committee disagrees with the office's
357	recommendation for corrective action, the records shall be referred to
358	the assistant commissioner for recommendation to the executive
359	commissioner.
360	
361	(E) If a facility disagrees with the office's recommendation at the end
362	of the secondary review, the facility has a right to a hearing, in
363	accordance with a hearing request referenced in §133.121(9) of this
364	title (relating to Enforcement Action), and Government Code, Chapter
365	2001.
366	C122 105 Duantum Danviusmants
367	§133.185 Program Requirements.
368	(a) Designated facilities shall have a family content whilesamby. The facility
369	(a) Designated facilities shall have a family centered philosophy. The facility
370	environment for perinatal care shall meet the physiologic and psychosocial
371	needs of the mothers, infants, and families. Parents shall have reasonable
372	access to their infants at all times and be encouraged to participate in the care of their infants.
373	care of their illiants.
374	(b) Program Plan. The facility shall develop a written plan of the maternal
375	(b) Program Plan. The facility shall develop a written plan of the maternal
376	program that includes a detailed description of the scope of services
377	available to all maternal patients, defines the maternal patient population evaluated and/or treated, transferred, or transported by the facility, that is
378 379	consistent with accepted professional standards of practice for maternal
379 380	care, and ensures the health and safety of patients.
381	care, and ensures the health and safety of patients.
382	(1) The written plan and the program policies and procedures shall
383	be reviewed and approved by the facility's governing body. The
384	governing body shall ensure that the requirements of this section
385	are implemented and enforced.
386	are implemented and emorced.
387	(2) The written maternal program plan shall include, at a minimum:
388	(2) The written maternal program plan shall melade, at a millimum.
389	(A) Program policies and procedures that are:
390	(7.7) Trogram pondes and procedures that are:
	(i) based upon current standards of maternal practices and
391	(i) based upon current standards of maternal practice; and

392 393	(ii) adopted, implemented and enforced for the maternal services it provides.
	services it provides.
394 395	(B) a periodic review and revision schedule for all maternal care
396	policies and procedures;
397	policies and procedures,
398	(C) written triage, stabilization, and transfer guidelines for
399	pregnant and postpartum women that include consultation and
400	transport services;
401	
402	(D) written guidelines or protocols for prevention, early
403	identification, early diagnosis, and therapy for conditions that
404	place the pregnant or postpartum woman at risk for morbidity
405	and/or mortality;
406	
407	(E) provisions for unit specific disaster response to include
408	evacuation of mothers and infants to appropriate levels of care;
409	
410	(F) a Quality Assessment and Performance Improvement (QAPI)
411	Program as described in §133.41(r) of this title (relating to
412	Hospital Functions and Services). The facility shall demonstrate
413	that the maternal program evaluates the provision of maternal
414	care on an ongoing basis, identify opportunities for
415	improvement, develop and implement improvement plans, and
416	evaluate the implementation until a resolution is achieved. The
417	Maternal program shall measure, analyze, and track quality
418	indicators and other aspects of performance that the facility
419	adopts or develops that reflect processes of care and is outcome
420	based. Evidence shall support that aggregate patient data is
421	continuously reviewed for trends and data is submitted to the
422	department as requested;
423	
424	(G) requirements for minimal credentials for all staff
425	participating in the care of maternal patients;
426	
427	(H) provisions for providing continuing staff education; including
428	annual competency and skills assessment that is appropriate for
429	the patient population served;
430	(I) a newigated staff registered names as a registerial staff registered
431	(I) a perinatal staff registered nurse as a representative on the
432	nurse staffing committee under §133.41(o)(2)(F) of this title;
433	and

435 436	(J) the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient
437 438	population served.
439 440 441	(c) Medical Staff. The facility shall have an organized maternal program that is recognized by the medical staff and approved by the facility's governing body.
442 443 444 445	(1)the credentialing of the maternal medical staff shall include a process for the delineation of privileges for maternal care.
446 447 448	(2)the maternal medical staff will participate in ongoing staff and team based education and training in the care of the maternal patient.
449 450 451 452	(d) Medical Director. There shall be an identified Maternal Medical Director (MMD) and/or Transport Medical Director (TMD) as appropriate, responsible for the provision of maternal care services and credentialed by the facility for the treatment of maternal patients.
453 454 455 456	(1) the responsibilities and authority of the MMD and TMD shall include but are not limited to:
457 458 459	 (A) examining qualifications of medical staff requesting maternal privileges and makes recommendations to the appropriate committee for such privileges;
460 461 462 463	 (B) assuring maternal medical staff competency in managing obstetrical emergencies, complications and resuscitation techniques;
464 465 466 467 468	(C) monitoring maternal patient care from transport if applicable, to admission, stabilization, operative intervention(s) if applicable, through discharge, and inclusive of the QAPI Program.
469 470 471	(D) participating in ongoing maternal staff and team based education and training in the care of the maternal patient;
472 473	(E) oversight of the inter-facility maternal transport;
474 475 476	(F) collaborates with the MPM in areas to include, but not limited to: developing and/or revising policies, procedures and quidelines, assuring staff competency, education and training.
477	guidelines, assuring staff competency, education and training;

478 479	the QAPI Program; and frequently participates in the maternal QAPI meeting;
480	3,
481	(G) ensuring that the QAPI Program is specific to maternal and
482	fetal care, is ongoing, data driven and outcome based;
483	(II) callaborates with the MDM to load the material OADI
484 485	(H) collaborates with the MPM to lead the maternal QAPI meeting;
485 486	meeting,
480 487	(I) frequent and active participation in maternal care at the
488	facility where medical director services are provided;
489	
490	(J) maintaining active staff privileges as defined in the facility's
491	medical staff bylaws; and
492	(IC) develope cellaborative valationaline with other MAND(s) of
493 404	(K) develops collaborative relationships with other MMD(s) of designated facilities within the applicable Perinatal Care Region.
494 495	designated racinities within the applicable Permatar Care Region.
496	(e) Maternal Program Manager (MPM). The MPM responsible for the provision
497	of maternal care services shall be identified by the facility and:
498	
499	(1) be a registered nurse;
500	
501	(2) have the authority and responsibility to monitor the provision of
502	maternal patient care services from admission, stabilization, operative
503	intervention(s) if applicable, through discharge, and inclusive of the QAPI Program as defined in subsection (b)(2)(E) of this section;
504 505	QAFI Frogram as defined in subsection (b)(2)(L) of this section,
505 506	(3) collaborate with the MMD in areas to include, but not limited to:
507	developing and/or revising policies, procedures and guidelines;
508	assuring staff competency, education, and training; the QAPI Program;
509	and frequently participates in the maternal QAPI meeting; and
510	
511	(4) develops collaborative relationships with other MPM(s) of
512	designated facilities within the applicable Perinatal Care Region.
513	§133.186 Maternal Designation Level I.
514 515	g133.186 Maternal Designation Level 1.
516 517	(a) Level I (Basic Care). The Level I maternal designated facility will:
518 519	 provide care of pregnant and postpartum women who are generally healthy, and do not have medical, surgical, or

520 521	obstetrical conditions that present a significant risk of maternal morbidity or mortality; and
522 523	(2) have skilled personnel with documented training, competencies
524 525	and annual continuing education specific for the patient population served.
526 527	(b) Maternal Medical Director (MMD). The MMD shall be a physician who:
528	
529 530	 is a family medicine physician or an obstetrics and gynecology physician, with training, experience and privileges in maternal care;
531	
532 533	(2) demonstrates administrative skills and oversight of the Quality Assessment and Performance Improvement (QAPI) Program; and
534	(2) has a smallest all a more largestications and section and self-the manufactured
535	(3) has completed annual continuing education specific to maternal
536	care.
537 538	(c) Program Function and Services
539	(e) Frogram Function and Services
540	(1) Triage and assessment of all patients admitted to the perinatal
541	service with:
542	
543	(A) identification of pregnant women who are at high risk of
544	delivering a neonate that requires a higher level of neonatal
545	care than the scope of their neonatal facility shall be
546	transferred to a higher level neonatal designated facility prior
547	to delivery unless the transfer is unsafe.
548	
549	(B) identification of pregnant or postpartum women with
550	conditions or complications that require a higher level of
551	maternal care shall be transferred to a higher level maternal
552	designated facility unless the transfer will be unsafe.
553 554	(2) The capability to care for women with uncomplicated pregnancies
555	and to stabilize and initiate management of unanticipated maternal-
556	fetal or maternal problems that occur during the antepartum,
557	intrapartum, or postpartum period until the patient can be transferred
558	to a higher level of neonatal and/or maternal care.
559	and the second s
560	(3) A board certified obstetrics and gynecology physician with
561	obstetrical training and experience will be available at all times.
562	- ·

563	(4) Medical, surgical and behavioral health specialists available for
564	consultation appropriate to the patient population served.
565	
566	(5) The ability to initiate an emergency cesarean delivery and ensure
567	the availability of a physician with the training, skills, and privileges to
568	perform the surgery within a time period consistent with current
569	standards of professional practice and maternal care.
570	
571	(6) Ensure that a qualified physician or certified nurse midwife with
572	appropriate physician back-up is available to attend all deliveries or
573	other obstetrical emergencies.
574	
575	(7) The primary physician or Certified Nurse Midwife with competence
576	in the care of pregnant women, whose credentials have been reviewed
577	by the MMD and is on call:
578	
579	(A) shall arrive at the patient's bedside within 30 minutes of an
580	urgent request;
581	
582	(B) if not immediately available to respond will be provided
583	appropriate backup coverage who shall be available, documented
584	in an on call schedule and readily available to facility staff;
585	
586	(C) the physician providing backup coverage shall arrive at the
587	patient's bedside within 30 minutes of an urgent request; and
588	
589	(D) has completed annual continuing education, specific to the
590	care of the pregnant and postpartum woman, including
591	complicated conditions.
592	
593	(8) Certified nurse midwives, physician assistant and nurse
594	practitioners who attend maternal patients:
595	
596	(A) Shall operate under guidelines reviewed and approved by the
597	MMD; and
598	
599	 (B) Shall have a formal arrangement with a physician with
600	obstetrics training and/or experience who will:
601	
602	(i) provide back-up and consultation;
603	
604	(ii) arrive at the patient's bedside within 30 minutes of an
605	urgent request; and
606	

607	(iii) meet requirements for Medical Staff as described in §
608	133.185 (c), (1) and (2) of this title respectively.
609	
610	(9) An on-call schedule of providers, back-up providers, and
611	provision for patients without a physician will be readily available to
612	facility and maternal staff and posted on the labor and delivery unit.
613	
614	(10) Availability of appropriate anesthesia, laboratory, pharmacy,
615	radiology, respiratory therapy, ultrasonography and blood bank
616	services on a 24 hour basis as described in § 133.41(a), (h), and (s) of
617	this title respectively.
618	
619	(A) Anesthesia personnel with obstetrical training and experience
620	will be available at all times and arrive to the patient's bedside
621	within 30 minutes of an urgent request.
622	
623	(B) Laboratory and blood bank services shall have guidelines or
624	protocols for:
625	
626	(i) massive blood product transfusion;
627	
628	(ii) emergency release of blood products; and
629	
630	(iii) management of multiple blood component therapy.
631	
632	(C) A pharmacist shall be available for consultation at all times.
633	
634	(D) Medical Imaging Services.
635	COTE IN THE COLUMN THE COLUMN
636	(i)If preliminary reading of imaging studies pending formal
637	interpretation is performed, the preliminary findings must
638	be documented in the medical record.
639	(ii) There recent he require requires of the preliminant
640	(ii)There must be regular monitoring of the preliminary
641	versus final reading in the QAPI Program.
642	(iii) Rasis ultrasanagraphis imaging for maternal or fotal
643	(iii) Basic ultrasonographic imaging for maternal or fetal
644	assessment including interpretation available at all times;
645	and
646	(iv) A portable ultraceund machine available in the labor
647 648	(iv) A portable ultrasound machine available in the labor
648 640	and delivery and antepartum unit.
649 650	(11) Obstatrical Sarvisos
650	(11) Obstetrical Services.

651	
652	(A) Ensure the availability and interpretation of non-stress
653	testing, and electronic fetal monitoring; and
654	
655	(B) A trial of labor for patients with prior cesarean delivery must
656	have the capability of anesthesia, cesarean delivery, and
657	maternal resuscitation onsite during the trial of labor.
658	
659	(12) Resuscitation. Written policies and procedures shall be specific to
660	the facility for the stabilization and resuscitation of pregnant or
661	postpartum women based on current standards of professional
662	practice.
663	
664	(13) Personnel must be immediately available onsite at all times who
665	demonstrate current status of successful completion of ACLS and the
666	skills to perform a complete resuscitation.
667	
668	(14) Ensure that resuscitation equipment including difficult airway
669	management equipment for pregnant and postpartum women is
670	readily available to the labor and delivery, antepartum and postpartum
671	areas.
672	
673	(15) The facility shall have written guidelines or protocols for various
674	conditions that place the pregnant or postpartum woman at risk for
675	morbidity and/or mortality, including promoting prevention, early
676	identification, early diagnosis, therapy, stabilization, and transfer. The
677	guidelines or protocols must address a minimum of:
678	
679	(A) Massive hemorrhage and transfusion of the pregnant or
680	postpartum patient in coordination of the blood bank, including
681	management of unanticipated hemorrhage and/or coagulopathy;
682	
683	(B) Obstetrical hemorrhage including promoting the identification
684	of patients at risk, early diagnosis, and therapy to reduce
685	morbidity and mortality;
686	
687	(C) Hypertensive disorders in pregnancy including eclampsia and
688	the postpartum patient to promote early diagnosis and
689	treatment to reduce morbidity and mortality;
690	•
691	(D) Sepsis and/or systemic infection in the pregnant or
692	postpartum woman;
693	,

694 695	(E) Venous thromboembolism in pregnant and postpartum women, and to assessment of risk factors, prevention, early
696	diagnosis and treatment; and
697	, , , , , , , , , , , , , , , , , , ,
698	(F) Shoulder dystocia including assessment of risk factors,
699	counseling of patient, and multi-disciplinary management.
700	
701	(16) Perinatal Education. A registered nurse with experience in
702	maternal care shall provide the supervision and coordination of staff
703	education. Perinatal education for high risk events will be provided at
704	frequent intervals to prepare medical, nursing, and ancillary staff for
705	these emergencies.
706	(17) Cupport parsonnal with knowledge and skills in breastfeeding and
707 708	(17) Support personnel with knowledge and skills in breastfeeding and lactation to meet the needs of mothers shall be available at all times.
708	lactation to meet the needs of mothers shall be available at all times.
710	(18) Social services, pastoral care and bereavement services shall be
711	provided as appropriate to meet the needs of the patient population
712	served.
713	
714	(19) Nutritionist or dietician available with appropriate training and
715	experience for population served in compliance with the requirements
716	in §133.41(d) of this title.
717	
718	§133.187 Maternal Designation Level II
719 720	(a)Level II (Specialty Care). The Level II maternal designated facility will:
721	(a)Level II (Specially Care). The Level II maternal designated radiity will.
722	(1) provide care for pregnant women and postpartum women with
723	medical, surgical, and/or obstetrical conditions that present a low to
724	moderate risk of maternal morbidity or mortality; and
725	
726	(2) have skilled personnel with documented training, competencies
727	and annual continuing education specific for the patient population
728	served.
729	(b) Matawal Madical Diverton (MMD). The MMD about he a physician when
730	(b) Maternal Medical Director (MMD). The MMD shall be a physician who:
731	(1) a family medicine physician, an obstetrics and gynecology
732 733	physician; or maternal fetal medicine physician, all with training,
734	experience and privileges in maternal care;
735	experience and privileges in material care,
736	(2) demonstrates administrative skills and oversight of the Quality
737	Assessment and Performance Improvement (QAPI) Program;

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- (3) has completed annual continuing education specific to maternal care including complicated conditions.
- (c) Program Function and Services
 - (1) Triage and assessment of all patients admitted to the perinatal service with:
 - (A) identification of pregnant women at high risk of delivering a neonate that requires a higher level of neonatal care than the scope of their neonatal facility shall be transferred to a higher level neonatal designated facility prior to delivery unless the transfer is unsafe; and
 - (B) identification of pregnant or postpartum women with conditions or complications that require a higher level of maternal care shall be transferred to a higher level maternal designated facility unless the transfer will be unsafe.
 - (2) Provide care for pregnant women with the capability to detect, stabilize, and initiate management of unanticipated maternal–fetal or maternal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a higher level of neonatal and/or maternal care.
 - (3) A board certified obstetrics and gynecology physician with obstetrical training and experience available at all times and arrives at the patient bedside within 30 minutes of an urgent request.
 - (4) A board certified maternal fetal medicine physician with obstetrical training and experience will be available at all times for consultation.
 - (5) Medical and surgical specialists available at all time and arrives at the patient bedside within 30 minutes of an urgent request.
 - (6) Specialists including behavioral health will be available for consultation appropriate to the patient population served.
 - (7) The ability to begin an emergency cesarean delivery and ensure the availability of a physician with the training, skills, and privileges to perform the surgery within a time period consistent with current standards of professional practice and maternal care.

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782 783	(8) Ensure that a qualified physician or certified nurse midwife with appropriate physician back-up is available to attend all deliveries or		
784	other obstetrical emergencies.		
785	j		
786	(9) The family medicine physician, obstetrician, maternal fetal		
787	medicine physician, or a certified nurse midwife with appropriate		
788	physician back-up, whose credentials have been reviewed by the MMD		
789	and is on call:		
790			
791	(A) shall arrive at the patient's bedside within 30 minutes of an		
792	urgent request;		
793			
794	(B) if not immediately available to respond will be provided		
795	appropriate backup coverage who shall be available, documented		
796	in an on call schedule and readily available to facility staff;		
797			
798	(C) the physician providing backup coverage shall arrive at the		
799	patient's bedside within 30 minutes of an urgent request; and		
800			
801	(D) has completed annual continuing education, specific to the		
802	care of the pregnant and postpartum woman, including		
803	complicated conditions.		
804			
805	(10) Certified nurse midwives, physician assistant and nurse		
806	practitioners who attend maternal patients:		
807			
808	(A) Shall operate under guidelines reviewed and approved by the		
809	MMD; and		
810			
811	(B) Shall have a formal arrangement with a physician with		
812	obstetrics training and/or experience who will:		
813			
814	(i) provide back-up and consultation;		
815			
816	(ii) arrive at the patient's bedside within 30 minutes of an		
817	urgent request; and		
818			
819	(iii) meet requirements for Medical Staff as described in §		
820	133.185 (c), (1) and (2) of this title respectively.		
821	(44) An an arthur dute of musical and the state of the st		
822	(11) An on-call schedule of providers, back-up providers, and provision		
823	for patients without a physician will be readily available to facility and		
824	maternal staff and posted on the labor and delivery unit.		
825			

826	(12) Availability of appropriate anesthesia, laboratory, pharmacy,		
827	radiology, respiratory therapy, ultrasonography and blood bank		
828	services on a 24 hour basis as described in § 133.41(a), (h), and (s) of		
829	this title respectively.		
830			
831	(13) Anesthesia Services shall:		
832			
833	(A) arrive to the patient's bedside within 30 minutes of an urgent		
834	request;		
835			
836	(B) have anesthesia personnel with obstetrical experience or		
837	training available at all times; and		
838			
839	(C) have an anesthesiologist with training or experience in		
840	obstetric anesthesia available at all times for consultation.		
841			
842	(14) Laboratory Services shall:		
843			
844	(A) Ensure the availability of ABO-Rh specific or O-Rh negative		
845	blood, fresh frozen plasma and/or cryoprecipitate, and platelet		
846	products at all times; and		
847			
848	(B) Ensure guidelines or protocols for:		
849			
850	(i) massive blood product transfusion;		
851	(ii) are a green with the page of blood and director and		
852	(ii) emergency release of blood products; and		
853	(iii) many same at a soutting a common and the graph		
854	(iii) management of multiple component therapy.		
855	(1E) A pharmacist shall be available for consultation at all times		
856	(15) A pharmacist shall be available for consultation at all times.		
857	(16) Modical Imaging		
858	(16) Medical Imaging.		
859	(A) If preliminary reading of imaging studies pending formal		
860	interpretation is performed, the preliminary findings must be		
861	documented in the medical record.		
862	documented in the medical record.		
863	(B) There must be regular monitoring of the preliminary versus		
864	final reading in the QAPI Program.		
865 866	iniai reading in the QAFI Flogram.		
866 867	(C) Computed Tomography (CT) imaging and interpretation		
868	available at all times.		
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870	(D) Ultrasound availability.
871	
872	(i) Basic ultrasonographic imaging for maternal or fetal
873	assessment and interpretation available at all times; and
874	
875	(ii) A portable ultrasound machine available in the labor
876	and delivery and antepartum unit for urgent bedside
877	examination.
878	
879	(17) Obstetrical Services.
880	
881	(A) Ensure the availability and interpretation of non-stress
882	testing, and electronic fetal monitoring; and
883	
884	(B) A trial of labor for patients with prior cesarean delivery must
885	have the immediate availability of anesthesia, cesarean delivery,
886	and maternal resuscitation capability during the trial of labor.
887	
888	(18) Resuscitation. Written policies and procedures shall be specific to
889	the facility for the stabilization and resuscitation of pregnant or
890	postpartum women based on current standards of professional
891	practice.
892	
893	(19) At least one person must be immediately available on site at all
894	times who demonstrates current status of successful completion of
895	ACLS and the skills to perform a complete resuscitation.
896	
897	(20) Ensure that resuscitation equipment including difficult airway
898	management equipment for pregnant and postpartum women is
899	readily available in the labor and delivery, antepartum and postpartum
900	areas.
901	
902	(21) The facility shall have written guidelines or protocols for various
903	conditions that place the pregnant or postpartum woman at risk for
904	morbidity and/or mortality, including promoting prevention, early
905	identification, early diagnosis, therapy, stabilization, and transfer. The
906	guidelines or protocols must address a minimum of:
907	
908	(A) Massive hemorrhage and transfusion of the pregnant or
909	postpartum patient in coordination of the blood bank, including
910	management of unanticipated hemorrhage and/or coagulopathy;
911	

912	(B) Obstetrical hemorrhage including promoting the identification		
913	of patients at risk, early diagnosis, and therapy to reduce		
914	morbidity and mortality;		
915			
916	(C) Hypertensive disorders in pregnancy including eclampsia and		
917	the postpartum patient to promote early diagnosis and		
918	treatment to reduce morbidity and mortality;		
919			
920	(D) Sepsis and/or systemic infection in the pregnant or		
921	postpartum woman;		
922			
923	(E) Venous thromboembolism in pregnant and postpartum		
924	women, and to assessment of risk factors, prevention, early		
925	diagnosis and treatment; and		
926			
927	(F) Shoulder dystocia including assessment of risk factors,		
928	counseling of patient, and multi-disciplinary management.		
929			
930	(22) The facility shall have nursing leadership and staff with formal		
931	training and experience in the provision of perinatal nursing care		
932	and should coordinate with respective neonatal services.		
933			
934	(23) Perinatal Education. A registered nurse with experience in		
935	maternal care including moderately complex and ill obstetric		
936	patients shall provide the supervision and coordination of staff		
937	education. Perinatal education for high risk events will be provided		
938	at frequent intervals to prepare medical, nursing, and ancillary staff		
939	for these emergencies.		
940			
941	(24) Support personnel with knowledge and skills in lactation and		
942	breastfeeding to meet the needs of mothers.		
943			
944	(25) Social services, pastoral care and bereavement services shall		
945	be provided as appropriate to meet the needs of the patient		
946	population served.		
947			
948	(26) Nutritionist or dietician available with appropriate training and		
949	experience for population served in compliance with the		
950	requirements in §133.41(d) of this title.		
951			
952	§133.188 Maternal Designation Level III		
953			
954	(a) A Level III (Subspecialty Care). The Level III maternal designated		
955	facility will:		

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956	
957	(1) provide care for pregnant and postpartum women with low
958	risk conditions to significant complex medical, surgical and/or
959	obstetrical conditions that present a high risk of maternal
960	morbidity or mortality;
961	
962	(2) ensure access to consultation to a full range of medical and
963	maternal subspecialists, surgical specialists, and behavioral health
964	specialists;
965	
966	(3) ensure capability to perform major surgery onsite;
967	
968	(4) have physicians with critical care training available at all times
969	to actively collaborate with Maternal Fetal Medicine physicians
970	and/or Obstetrics and Gynecology Physicians with obstetrical
971	training and privileges;
972	
973	(5) have skilled personnel with documented training,
974	competencies and annual continuing education, specific for the
975	population served;
976	
977	(6) facilitate transports; and
978	
979	(7) provide outreach education to lower level designated facilities
980	including the Quality Assessment and Performance Improvement
981	(QAPI) process.
982	
983	(b) Maternal Medical Director (MMD). The MMD shall be a physician who:
984	
985	(1) is a board certified obstetrics and gynecology physician with
986	obstetrical training and experience; or board certified maternal fetal
987	medicine physician;
988	
989	(2) demonstrates administrative skills and oversight of the Quality
990	Assessment and Performance Improvement (QAPI) Program; and
991	
992	(3) has completed annual continuing education specific to maternal
993	care including complicated conditions;
994	
995	(c) If the facility has its own transport program, there shall be an identified
996	Transport Medical Director (TMD). The TMD shall be a physician who is a
997	board /certified maternal fetal medicine specialist or board certified
998	obstetrics and gynecology physician with privileges and experience in
999	obstetrical care and maternal transport.

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- (d) Program Function and Services.
 - (1) Triage and assessment of all patients admitted to the perinatal service with:
 - (A) identification of pregnant women who are at high risk of delivering a neonate that requires a higher level of neonatal care shall be transferred to a higher level neonatal designated facility prior to delivery unless the transfer is unsafe;
 - (B) identification of pregnant or postpartum women with conditions and/or complications that will require a higher level of maternal care will be transferred to a higher level maternal designated facility unless the transfer will be unsafe;
 - (C) have the capability to detect, stabilize, and initiate management of unanticipated maternal–fetal or maternal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a higher level of maternal and/or maternal care;
 - (D) Supportive and emergency care delivered by appropriately trained personnel for unanticipated maternal-fetal problems that occur until the patient is stabilized or transferred;
 - (E) The ability to begin an emergency cesarean delivery within a time period consistent with current standards of professional practice and maternal care; and
 - (F) Ensure that a qualified physician, or a certified nurse midwife with appropriate physician back-up, is available to attend all deliveries or other obstetrical emergencies.
 - (2) The primary provider caring for a pregnant or postpartum woman who is a family medicine physician, obstetrician, maternal fetal medicine physician, or a certified nurse midwife with appropriate physician back-up, whose credentials have been reviewed by the MMD and is on call:
 - (A) shall arrive at the patient's bedside within 30 minutes for an urgent request;

1043	(B) if not immediately available to respond will be provided
1044	appropriate backup coverage who shall be available, documented
1045	in an on call schedule and readily available to facility staff;
1046	
1047	(C) ensure that the physician providing backup coverage shall
1048	arrive at patient's bedside within 30 minutes for an urgent
1049	consult; and
1050	
1051	(D) has completed annual continuing education, specific to the
1052	care of the pregnant and postpartum women.
1053	
1054	(3) Certified nurse midwives, physician assistants and nurse
1055	practitioners who attend maternal patients:
1056	
1057	(A) shall operate under guidelines reviewed and approved by the
1058	MMD; and
1059	
1060	(B) shall have a formal arrangement with a physician with
1061	obstetrics training and/or experience who will:
1062	
1063	(i) provide back-up and consultation;
1064	
1065	(ii) arrive at the patient's bedside within 30 minutes of an
1066	urgent request; and
1067	
1068	(iii) meet requirements for Medical Staff as described in §
1069	133.185 (c), (1) and (2) of this title respectively.
1070	
1071	(4) A board certified obstetrician or board eligible/certified maternal
1072	fetal medicine physician shall be on-site and available at all times for
1073	urgent situations.
1074	
1075	(5) Medical and surgical physicians shall be available at all times and
1076	arrives at the patient bedside within 30 minutes of an urgent request.
1077	
1078	(6) An on-call schedule of providers, back-up providers, and provision
1079	for patients without a physician will be readily available to facility and
1080	maternal staff and posted on the labor and delivery unit.
1081	
1082	(7) Anesthesia Services shall be in compliance with the requirements
1083	found at § 133.41(a) of this title and shall have:
1084	
1085	(A) anesthesia personnel with obstetrical experience and
1086	expertise shall be available onsite at all times;

1087		
1088	(B)	a board certified anesthesiologist with training or
1089		experience in obstetric anesthesia is in charge of obstetric
1090		anesthesia services;
1091		
1092	(C)	a board certified anesthesiologist with training or
1093		experience in obstetric anesthesia including critically ill
1094		obstetric patients available for consultation at all times,
1095		and arrive at the patient's bedside for urgent requests
1096		within 30 minutes; and
1097		
1098	(D) a	nesthesia personnel on call, including back-up contact
1099	inforr	mation, posted and readily available to the facility and
1100	mate	rnal staff and posted on the labor and delivery area.
1101		
1102	(8) Labora	tory Services shall be in compliance with the requirements
1103	found at §	133.41(h) of this title and shall have:
1104		
1105	(A) la	aboratory personnel onsite at all times.
1106		
1107	(B) a	blood bank capable of:
1108		
1109		(i) providing ABO-Rh specific or O-Rh negative blood, fresh
1110		frozen plasma and cryoprecipitate, and platelet products
1111		onsite at the facility at all times;
1112		
1113		(ii) implementing a massive transfusion protocol;
1114		
1115		(iii) ensuring guidelines for emergency release of blood
1116		products; and
1117		
1118		(iv) managing multiple component therapy; and
1119		
1120	(C) p	erinatal pathology services available.
1121		
1122	• •	Imaging Services shall be in compliance with the
1123	requiremer	its found at § 133.41(h) of this title and shall have:
1124		
1125		ersonnel appropriately trained in the use of x-ray
1126	equip	oment available onsite at all times;
1127		
1128		dvanced imaging including computed tomography (CT),
1129		netic resonance imaging(MRI), and echocardiography
1130	availa	able at all times;

1131	
1132	(C) interpretation of CT, MRI and echocardiography within 1 hour
1133	of the completed study for urgent requests;
1134	
1135	(D) basic ultrasonographic imaging for maternal or fetal
1136	assessment including interpretation available at all times; and
1137	
1138	(E) a portable ultrasound machine available in the labor and
1139	delivery and antepartum unit.
1140	
1141	(10) Respiratory Therapy Services shall be in compliance with the
1142	requirements found at § 133.41(h) of this title and have a respiratory
1143	therapist immediately available on-site at all times.
1144	
1145	(11) Obstetrical Services.
1146	
1147	(A) Ensure the availability and interpretation of non-stress
1148	testing, and electronic fetal monitoring.
1149	
1150	(B) A trial of labor for patients with prior cesarean delivery must
1151	have the immediate availability of anesthesia, cesarean delivery,
1152	and maternal resuscitation capability during the trial of labor.
1153	
1154	(12) Pharmacy services shall be in compliance with the
1155	requirements found in § 133.41 (q) of this title and will have a
1156	pharmacist with experience in perinatal pharmacology onsite and
1157	available at all times.
1158	
1159	(13) Intensive Care Services. The facility shall provide critical
1160	care services for critically ill pregnant or postpartum women,
1161	including fetal monitoring in the ICU, respiratory failure and
1162	ventilator support, procedure for emergency cesarean,
1163	coordination of nursing care, and consultative or co-management
1164	roles to facilitate collaboration.
1165	
1166	(14) Resuscitation. Written policies and procedures shall be specific to
1167	the facility for the stabilization and resuscitation of pregnant or
1168	postpartum women based on current standards of professional
1169	practice.
1170	
1171	(15) Staff members must be immediately available on site at all times
1172	who demonstrates current status of successful completion of ACLS and
1173	the skills to perform a complete resuscitation.

1175	(16) Ensure that resuscitation equipment including difficult airway
1176	management equipment for pregnant and postpartum women is
1177	readily available in the labor and delivery, antepartum and postpartum
1178	areas.
1179	
1180	(17) The facility shall have written guidelines or protocols for various
1181	conditions that place the pregnant or postpartum woman at risk for
1182	morbidity and/or mortality, including promoting prevention, early
1183	identification, early diagnosis, therapy, stabilization, and transfer. The
1184	guidelines or protocols must address a minimum of:
1185	
1186	(A) massive hemorrhage and transfusion of the pregnant or
1187	postpartum patient in coordination of the blood bank, including
1188	management of unanticipated hemorrhage and/or coagulopathy;
1189	
1190	(B) obstetrical hemorrhage including promoting the identification
1191	of patients at risk, early diagnosis, and therapy to reduce
1192	morbidity and mortality;
1193	
1194	(C) hypertensive disorders in pregnancy including eclampsia and
1195	the postpartum patient to promote early diagnosis and
1196	treatment to reduce morbidity and mortality;
1197	
1198	(D) sepsis and/or systemic infection in the pregnant or
1199	postpartum woman;
1200	
1201	(E) venous thromboembolism in pregnant and postpartum
1202	women, and to assessment of risk factors, prevention, early
1203	diagnosis and treatment; and
1204	
1205	(F) shoulder dystocia including assessment of risk factors,
1206	counseling of patient, and multi-disciplinary management.
1207	
1208	
1209	(18) The facility shall have nursing leadership and staff with training
1210	and experience in the provision of perinatal nursing care and shall
1211	coordinate with respective neonatal services.
1212	(40) 01 111
1213	(19) Shall have a program for genetic diagnosis and counseling for
1214	genetic disorders, or a policy and process for consultation referral to
1215	an appropriate facility.
1216	
1217	(20) Perinatal Education. A registered nurse with experience in
1218	maternal care including moderately complex and ill obstetric patients

1219	shall provide the supervision and coordination of staff education.
1220	Perinatal education for high risk events will be provided at frequent
1221	intervals to prepare medical, nursing, and ancillary staff for these
1222	emergencies.
1223	
1224	(21) Support personnel with knowledge and skills in breastfeeding to
1225	meet the needs of mothers shall be available at all times.
1226	
1227	(22) A certified lactation consultant shall be available at all times.
1228	
1229	(23) Social services, pastoral care and bereavement services shall be
1230	provided as appropriate to meet the needs of the patient population
1231	served.
1232	
1233	(24) A dietician or nutritionist who has training or experience in
1234	perinatal nutrition and can plan diets that meet the needs of the
1235	pregnant woman in compliance with the requirements in § 133.41(d)
1236	of this title.
1237	
1238	§133.189 Maternal Designation Level IV
1239	(a) A Laval IV (Camanahanaiya Caya). The Laval IV material designated
1240	(a) A Level IV (Comprehensive Care). The Level IV maternal designated
1241	facility will:
1242	(1) provide peripatal wemen with comprehensive care for low rick
1243 1244	(1) provide perinatal women with comprehensive care for low risk conditions to the most complex medical, surgical and/or obstetrical
1244	conditions and their fetuses, that present a high risk of maternal
1245	morbidity or mortality;
1247	morbialty of mortality,
1248	(2) ensure access to on site consultation to a comprehensive range of
1249	medical and maternal subspecialists, surgical specialists, and
1250	behavioral health specialists, and the capability to perform major
1251	surgery onsite;
1252	surgery onsite,
1253	(3) have skilled personnel with documented training, competencies
1254	and annual continuing education, specific for the patient population
1255	served;
1256	
1257	(4) facilitate transports; and
1258	(,
1259	(5) provide outreach education to lower level designated facilities
1260	including the Quality Assessment and Performance Improvement

(QAPI) process.

1263	(b) Maternal Medical Director (MMD). The MMD shall be a physician who:
1264	
1265	(1) is board certified in obstetrics and gynecology with expertise in the
1266	area of critical care obstetrics; or board certified in maternal fetal
1267	medicine;
1268	
1269	(2) demonstrates administrative skills and oversight of the Quality
1270	Assessment and Performance Improvement (QAPI) Program; and
1271	
1272	(3) has completed annual continuing education annually specific to
1273	maternal care including complicated conditions.
1274	
1275	(c) If the facility has its own transport program, there shall be an identified
1276	Transport Medical Director (TMD). The TMD shall be a physician who is a
1277	board certified maternal fetal medicine physician or board certified obstetrics
1278	and gynecology physician with obstetrics privileges, with expertise and
1279	experience in critically ill maternal transport.
1280	
1281	(d) Program Function and Services.
1282	
1283	(1) Triage and assessment of all patients admitted to the perinatal
1284	service with:
1285	
1286	(A) identification of pregnant women who are at high risk of
1287	delivering a neonate that requires a higher level of neonatal care
1288	shall be transferred to a higher level neonatal designated facility
1289	prior to delivery unless the transfer is unsafe; and
1290	
1291	(B) identification of pregnant or postpartum women with
1292	conditions and/or complications that require a service not
1293	available at the facility, will be transferred to an appropriate
1294	maternal designated facility unless the transfer will be unsafe.
1295	
1296	(2) Supportive and emergency care shall be delivered by appropriately
1297	trained personnel, for unanticipated maternal-fetal problems that
1298	occur during labor and delivery, through the disposition of the patient.
1299	
1300	(3) Ensure that a qualified physician, or a certified nurse midwife with
1301	appropriate physician back-up, is available to attend all deliveries or
1302	other obstetrical emergencies.
1303	
1304	(4) The ability to begin an emergency cesarean delivery within a time
1305	period consistent with current standards of professional practice and
1306	maternal care.

1307		
1308	` ' '	mary provider caring for a pregnant or postpartum woman
1309		mily medicine physician, obstetrician, or maternal fetal
1310	•	hysician, or a certified nurse midwife, physician assistant or
1311	•	itioner with appropriate physician back-up, whose
1312	credentials	have been reviewed by the MMD and:
1313		
1314	(A)	shall arrive at the patient's bedside within 30 minutes for
1315		an urgent request;
1316		
1317	(B)	if not immediately available to respond will be provided
1318		appropriate backup coverage who shall be available,
1319		documented in an on call schedule and readily available to
1320		facility staff;
1321		
1322	(C)	ensure that the physician providing backup coverage shall
1323		arrive at the patient bedside within 30 minutes for an
1324		urgent request; and
1325		
1326	(D) h	as completed annual continuing education, specific to the
1327	care	of the pregnant and postpartum woman, including
1328	comp	licated and critical conditions.
1329		
1330	(6) Certifie	d nurse midwives, physician assistants and nurse
1331	practitioner	rs who provide care for maternal patients:
1332		
1333	(A) S	hall operate under guidelines reviewed and approved by the
1334	MMD	; and
1335		
1336	(B) S	hall have a formal arrangement with a physician with
1337	obste	etrics training and/or experience who will:
1338		
1339		(i) provide back-up and consultation;
1340		
1341		(ii) arrive at the patient's bedside within 30 minutes of an
1342		urgent request; and
1343		
1344		(iii) meet requirements for Medical Staff as described in §
1345		133.185 (c), (1) and (2) of this title respectively.
1346		•
1347	(7) A boar	d certified gynecology and obstetrics physician with
1348		privileges shall be on-site at all times.
1349		

1350 1351	(8) An on-call schedule of providers, back-up providers, and provision for patients without a physician will be readily available to facility and
1352	maternal staff and posted on the labor and delivery unit.
1353	
1354	(9) Anesthesia Services shall be in compliance with the requirements
1355	found at § 133.41(h) of this title and shall have:
1356	(A) anosthosis personnel with shotatrical experience and
1357	(A) anesthesia personnel with obstetrical experience and expertise available onsite at all times;
1358 1359	expertise available offsite at all times,
1360	(B) a board certified anesthesiologist with training and/or
1361	experience in obstetric anesthesia in charge of obstetric
1362	anesthesia services;
1363	
1364	(C) a board certified anesthesiologist with training or experience
1365	in obstetric anesthesia including critically ill obstetric patients
1366	available for consultation at all times, and arrive at the patient's
1367	bedside for urgent requests within 30 minutes; and
1368	
1369	(D) anesthesia personnel on call, including back-up contact
1370	information, posted and readily available to the facility and
1371	maternal staff and posted on the labor and delivery area.
1372	
1373	(10) Laboratory Services shall be in compliance with the requirements
1374	found at § 133.41(h) of this title and shall have:
1375	
1376	(A) Laboratory personnel onsite at all times;
1377	(B) A blood bank capable of:
1378 1379	(b) A blood bank capable of.
1380	(i) providing ABO-Rh specific or O-Rh negative blood, fresh
1381	frozen plasma and cryoprecipitate, and platelet products
1382	onsite at all times;
1383	
1384	(ii) implementing a massive transfusion protocol;
1385	
1386	(iii) ensuring guidelines for emergency release of blood
1387	products; and
1388	
1389	(iv) managing multiple component therapy.
1390	
1391	(C) Perinatal pathology services are available.
1392	

1393	(11) Medical Imaging Services shall be in compliance with the
1394	requirements found at § 133.41(h) of this title and shall have:
1395	
1396	(A) personnel appropriately trained in the use of x-ray
1397	equipment available on-site at all times;
1398	(D)
1399	(B) advanced imaging including computed tomography (CT),
1400	magnetic resonance imaging(MRI), and echocardiography
1401	available at all times;
1402	(C) intermediation of CT MDI and advantage with its 1
1403	(C) interpretation of CT, MRI and echocardiography within 1
1404	hour on completion of the study for urgent requests;
1405	
1406	(D) a radiologist with critical interventional radiology skills
1407	available at all times;
1408	
1409	(E) basic ultrasonographic imaging for maternal or fetal
1410	assessment including interpretation available at all times; and
1411	
1412	(F) a portable ultrasound machine available in the labor and
1413	delivery and antepartum unit.
1414	(12) Describe to the Theorem Commisses that the improved in the wilder
1415	(12) Respiratory Therapy Services shall be in compliance with the
1416	requirements found at § 133.41(h) of this title and shall have a
1417	respiratory therapist immediately available on-site at all times.
1418	(12) Obstatuical Comicas
1419	(13) Obstetrical Services.
1420	(A) Engure the availability and interpretation of non-stress
1421	(A) Ensure the availability and interpretation of non-stress
1422	testing, and electronic fetal monitoring.
1423	(P) A trial of labor for nationts with prior cocaroan delivery must
1424	(B) A trial of labor for patients with prior cesarean delivery must
1425	have anesthesia, cesarean delivery, and maternal resuscitation
1426	capability onsite during the trial of labor.
1427	(14) Pharmacy services shall be in compliance with the requirements
1428 1429	found in § 133.41 (q) of this title and will have a pharmacist with
	experience in perinatal pharmacology onsite and available at all times.
1430	experience in permatai pharmacology offsite and available at all times.
1431 1432	(15) Intensive Care Services. The facility shall have onsite ICU
	care for obstetric patients with onsite medical and surgical care,
1433	in collaboration with the Maternal Fetal Medicine Critical Care
1434	
1435	Team.
1436	

1437	(16) Maternal Fetal Medicine Critical Care Team. The facility shall have
1438	a Maternal Fetal Medicine (MFM) critical care team with expertise to
1439	assume responsibility for pregnant women and women in the
1440	postpartum period who are in critical condition or have complex
1441	medical conditions including;
1442	
1443	(A) co-management of ICU-admitted obstetric patients;
1444	
1445	(B) an MFM team member with full obstetrical privileges
1446	available at all times for on-site consultation and management;
1447	and
1448	
1449	(C) the team must be led by a board-certified MFM with
1450	expertise in critical care obstetrics.
1451	
1452	(17) Management of critically ill pregnant or postpartum women,
1453	including fetal monitoring in the ICU, respiratory failure and ventilator
1454	support, procedure for emergency cesarean, coordination of nursing
1455	care, and consultative or co-management roles to facilitate
1456	collaboration.
1457	
1458	(18) Resuscitation. Written policies and procedures shall be specific to
1459	the facility for the stabilization and resuscitation of pregnant or
1460	postpartum women based on current standards of professional
1461	practice.
1462	
1463	(19) Staff members must be immediately available on site at all times
1464	who demonstrate current status of successful completion of ACLS and
1465	the skills to perform a complete resuscitation.
1466	
1467	(20) Ensure that resuscitation equipment including difficult airway
1468	management equipment for pregnant and postpartum women is
1469	readily available in the labor and delivery, antepartum and postpartum
1470	areas.
1471	
1472	(21) The facility shall have written guidelines or protocols for various
1473	conditions that place the pregnant or postpartum woman at risk for
1474	morbidity and/or mortality, including promoting prevention, early
1475	identification, early diagnosis, therapy, stabilization, and transfer. The
1476	guidelines or protocols must address a minimum of:
1477	
1478	(A) massive hemorrhage and transfusion of the pregnant or
1479	postpartum patient in coordination of the blood bank, including
1480	management of unanticipated hemorrhage and/or coagulopathy;

1481	
1482	(B) obstetrical hemorrhage including promoting the identification
1483	of patients at risk, early diagnosis, and therapy to reduce
1484	morbidity and mortality;
1485	
1486	(C) hypertensive disorders in pregnancy including eclampsia and
1487	the postpartum patient to promote early diagnosis and
1488	treatment to reduce morbidity and mortality;
1489	
1490	(D) sepsis and/or systemic infection in the pregnant or
1491	postpartum woman;
1492	
1493	(E) venous thromboembolism in pregnant and postpartum
1494	women, and to assessment of risk factors, prevention, early
1495	diagnosis and treatment; and
1496	
1497	(F) shoulder dystocia including assessment of risk factors,
1498	counseling of patient, and multi-disciplinary management;
1499	
1500	(22) The facility shall have nursing leadership and staff with training
1501	and experience in maternal critical care and will coordinate with
1502	respective neonatal services.
1503	
1504	(23) Behavioral Health Services.
1505	
1506	(A) Consultation by a behavioral health professional, with
1507	experience in maternal and/or neonatal counseling shall be
1508	available onsite at all times for face-to-face visits when
1509	requested for prenatal, peri-operative, and postnatal needs of
1510	the patient within a time period consistent with current
1511	standards of professional practice and maternal care.
1512	
1513	(B) Consultation by a board certified psychiatrist, with
1514	experience in maternal and/or neonatal counseling shall be
1515	available for face-to-face visits when requested within a time
1516	period consistent with current standards of professional practice
1517	and maternal care.
1518	
1519	(24) Shall have a program for genetic diagnosis and counseling for
1520	genetic disorders, or a policy and process for consultation referral to
1521	an appropriate facility.
1522	
1523	(25) Perinatal Education. A registered nurse with experience in
1524	maternal care including moderately complex and ill obstetric patients

shall provide the supervision and coordination of staff education. Perinatal education for high risk events will be provided at frequent intervals to prepare medical, nursing, and ancillary staff for these emergencies.

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(26) Support personnel with knowledge and skills in breastfeeding to meet the needs of mothers shall be available at all times.

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(27) A certified lactation consultant shall be available at all times

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(28) Social services, pastoral care and bereavement services shall be provided as appropriate to meet the needs of the patient population served.

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(29) A dietician or nutritionist who has training and experience in maternal nutrition and can plan diets that meet the needs of the pregnant woman and critically ill maternal patients in compliance with the requirements in § 133.41(d) of this title.

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§133.190 Survey Team

1546 1547 1548 (a)The survey team composition shall be as follows:

1549 1550 (1) Level I facilities maternal program staff shall conduct a self-survey, documenting the findings on the approved office survey form. The office may periodically require validation of the survey findings, by an on-site review conducted by department staff.

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(2) Level II facilities shall be surveyed by a team that is multidisciplinary and includes at a minimum of one obstetrics and gynecology physician and one maternal nurse, all approved in advance by the office and currently active in the management of maternal patients at a facility providing the same or a higher level of maternal care.

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(3) Level III facilities shall be surveyed by a team that is multidisciplinary and includes at a minimum of one obstetrics and gynecology physician or maternal fetal medicine physician and one maternal nurse, all approved in advance by the office and currently active in the management of maternal patients at a facility providing the same or a higher level of maternal care. An additional surveyor may be requested by the facility or at the discretion of the office.

1568	(4) Level IV facilities shall be surveyed by a team that is multi-
1569	disciplinary and includes at a minimum of one obstetrics and
1570	gynecology physician, a maternal fetal medicine physician and one
1571	maternal nurse, all approved in advance by the office and currently
1572	active in the management of maternal patients at a facility providing
1573	the same level of maternal care.
1574	
1575	(b) Office-credentialed surveyors must meet the following criteria:
1576	
1577	(1) have at least three years of experience in the care of maternal
1578	patients;
1579	
1580	(2) be currently employed and practicing in the coordination of care for
1581	maternal patients;
1582	
1583	(3) have direct experience in the preparation for and successful
1584	completion of maternal facility verification and/or designation;
1585	
1586	(4) have successfully completed an office-approved maternal facility
1587	site surveyor course and be successfully re-credentialed every four
1588	years; and
1589	
1590	(5) have current credentials as follows:
1591	
1592	(A) a registered nurse who has successfully completed an office
1593	approved site survey internship; or
1594	
1595	(B) a physician who is board certified in the respective specialty,
1596	and has successfully completed an office approved site survey
1597	internship.
1598	
1599	(c) All members of the survey team, except department staff, shall come
1600	from a Perinatal Care Region outside the facility's location and at least 100
1601	miles from the facility. There shall be no business or patient care relationship
1602	or any potential conflict of interest between the surveyor or the surveyor's
1603	place of employment and the facility being surveyed.
1604	
1605	(d) The survey team shall evaluate the facility's compliance with the
1606	designation criteria by:
1607	
1608	(1) reviewing medical records; staff rosters and schedules;
1609	documentation of QAPI Program activities including peer review; the
1610	program plan; policies and procedures; and other documents relevant

to maternal care;

Maternal Rules Draft Document

1612	
1613	(2) reviewing equipment and the physical plant;
1614	
1615	(3) conducting interviews with facility personnel; surveyors may meet
1616	privately with individuals or groups of personnel; and
1617	
1618	(4) evaluating appropriate use of telemedicine capabilities where
1619	applicable.
1620	
1621	(e) All information and materials submitted by a facility to the office under
1622	Health and Safety Code, §241.183(d), are subject to confidentiality as
1623	articulated in Health and Safety Code, §241.184, Confidentially; Privilege,
1624	and are not subject to disclosure under Government Code, Chapter 552, or
1625	discovery, subpoena, or other means of legal compulsion for release to any
1626	person.
1627	
1628	